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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,211	09/09/2003	Florian Lang	WWELL73.005AUS	2719

20995 7590 10/20/2005

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EXAMINER

HAMA, JOANNE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,211	LANG ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Application, filed September 9, 2003, claims no additional priority.

Claims 1-57 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to an in vitro method for identifying a hair growth modulating substance, comprising:
 - a) contacting a peptide derived from SGK3 and a test substance suspected to modulate hair growth, under conditions allowing the binding of said test substance to said peptide, and
 - b) determining whether said test substance modulates an activity of said peptide,wherein said test substance inhibits or stimulates the kinase activity of said peptide, classified in class 514, subclass 1.
- II. Claims 16-20, drawn to an in vivo method for identifying a hair growth modulating substance comprising:
 - a) providing a transgenic non-human *sgk3*^{-/-} animal,
 - b) administering a test substance to said animal, and
 - c) determining whether said test substance modulates hair growth of said animal, classified in class 800, subclass 3.
- III. Claims 5-8, 21-24, 45-48, drawn to a method for preparing a pharmaceutical/cosmetic composition for a treatment of a hair growth disorder, comprising:

- a) providing a hair growth modulating substance,
 - b) formulating said substance into a pharmaceutically/cosmetically acceptable carrier, classified in class 514, subclass 1.
- IV. Claims 10-12, 26-28, drawn to a method for treating a human being affected by a hair growth disorder, comprising administering a hair growth modulating substance, wherein the hair growth modulating substance is a chemical compound, classified in class 514, subclass 1.
- V. Claims 10-12, 26-28, 34-38, drawn to a method for treating a human being affected by a hair growth disorder, comprising administering a hair growth modulating substance, wherein the hair growth modulating substance is construct coding for an antisense-sgk-3 probe, classified in class 514, subclass 44.
- VI. Claims 10-12, 26-28, 34-38, drawn to a method for treating a human being affected by a hair growth disorder, comprising administering a hair growth modulating substance, wherein the hair growth modulating substance is a construct coding for sgk-3 RNAi, classified in class 514, subclass 44.
- VII. Claims 10-12, 26-28, 34-38, drawn to a method for treating a human being affected by a hair growth disorder, comprising administering a hair growth modulating substance, wherein the hair growth modulating substance is a nucleic acid that encodes a transdominant inhibitory SGK3, classified in class 514, subclass 44.

- VIII. Claims 10-12, 26-28, 39-44, drawn to a method for treating a human being affected by a hair growth disorder, comprising administering a hair growth modulating substance, wherein the hair growth modulating substance is a genetic construct comprising a coding region coding for sgk-3-derived segment under control of a promoter, classified in class 514, subclass 44.
- IX. Claims 14, 30, 50-57, drawn to a hair growth modulating substance that inhibits activity of SGK-3, wherein the substance is a chemical compound, classified in class 514, subclass 1.
- X. Claims 14, 30, 50-57, drawn to a hair growth modulating substance that inhibits activity of SGK-3, wherein the substance is a nucleic acid, wherein the nucleic acid is a construct coding for an antisense-sgk-3 probe, classified in class 514, subclass 44.
- XI. Claims 14, 30, 50-57, drawn to a hair growth modulating substance that inhibits activity of SGK-3, wherein the substance is a nucleic acid, wherein the nucleic acid is a construct coding for skg-3RNAi, classified in class 514, subclass 44.
- XII. Claims 14, 30, 50-57, drawn to a hair growth modulating substance that inhibits activity of SGK-3, wherein the substance is a nucleic acid, wherein the nucleic acid is a construct that encodes a transdominant inhibitory SGK3, classified in class 514, subclass 44.
- XIII. Claims 14, 30, 50-57, drawn to a hair growth modulating substance that inhibits activity of SGK-3, wherein the substance is a nucleic acid, wherein

the nucleic acid is a genetic construct comprising a coding region coding for sgk-3-derived segment under control of a promoter, classified in class 514, subclass 44.

- XIV. Claims 14, 30, 50-57, drawn to a hair growth modulating substance that inhibits activity of SGK-3, wherein the substance is a protein, classified in class 530, subclass 300.
- XV. Claims 15, 31, 50-57, drawn to a hair growth modulating substance that stimulates activity of SGK-3, wherein the substance is a chemical compound, classified in class 514, subclass 1.
- XVI. Claims 15, 31, 50-57, drawn to a hair growth modulating substance that stimulates activity of SGK-3, wherein the substance is a nucleic acid construct coding for an antisense-sgk-3 probe, classified in class 514, subclass 44.
- XVII. Claims 15, 31, 50-57, drawn to a hair growth modulating substance that stimulates activity of SGK-3, wherein the substance is a nucleic acid, wherein the nucleic acid is a construct coding for skg-3RNAi, classified in class 514, subclass 44.
- XVIII. Claims 15, 31, 50-57, drawn to a hair growth modulating substance that stimulates activity of SGK-3, wherein the substance is a nucleic acid, wherein the nucleic acid is a construct that encodes a transdominant inhibitory SGK3, classified in class 514, subclass 44.

- XIX. Claims 15, 31, 50-57, drawn to a hair growth modulating substance that stimulates activity of SGK-3, wherein the substance is a nucleic acid, wherein the nucleic acid is a genetic construct comprising a coding region coding for sgk-3-derived segment under control of a promoter, classified in class 514, subclass 44.
- XX. Claims 15, 31, 50-57, drawn to a hair growth modulating substance that stimulates activity of SGK-3, wherein the substance is a protein, classified in class 530, subclass 300.
- XXI. Claims 32, 33, drawn to a transgenic non-human sgk3^{-/-} animal, classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Claims 9 and 25 link Inventions IV-VIII.

Claims 13, 29, and 49 link Inventions IX-XX.

The restriction requirement amongst the linked inventions is subject to the nonallowance of the linking claim(s), claims 9 and 25 for Inventions IV-VIII and claims 13, 29, and 49 for Inventions IX-XX. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the

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continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II are patentably distinct. While both inventions are drawn to a method for identifying a hair growth modulating substance, Invention I is drawn to an in vitro method, whereas Invention II is drawn to in vivo method. These methods comprise unique steps. The searches for Inventions I and II are burdensome because the searches are not coextensive.

Inventions IV-VIII are patentably distinct. While these Inventions are similarly drawn to a method for treating a human being affected by a hair growth disorder, comprising a step of administering a hair growth modulating substance, the substances administered to the patient are distinct because they comprise unique structures. The searches for Inventions IV-VIII are burdensome because the searches are not coextensive.

Inventions IX-XX are patentably distinct. While these Inventions are similarly drawn to a hair growth modulating substance, Inventions IX-XIV are substances that inhibit activity of SGK-3, while Inventions XV-XX are substances that stimulates activity of SGK-3. These are two distinct differences in activity. Inventions IX-XIV are distinct from each other because while they are to substances that inhibit activity of SGK-3,

each of the substances are comprised of unique structures. Similarly, Inventions XV-XX are distinct from each other because each of the substances are comprised of unique structures. The searches for Inventions IX-XX are burdensome because the searches are not coextensive.

Inventions I/II and III are patentably distinct. Inventions I/II are drawn to a method for identifying a substance that modulates hair growth; Invention III is drawn to a method for preparing a pharmaceutical/cosmetic composition comprising a hair growth modulating substance, for a treatment of a hair growth disorder. While the methods are commonly drawn to hair growth modulating substance, the method steps in screening for substances and in preparing a pharmaceutical/cosmetic composition are different. The searches for Inventions I/II and III are burdensome because the searches are not coextensive.

Inventions I/II/III and IV-VIII are patentably distinct. While Inventions I/II/III are drawn to methods of identifying a substance that modulates hair growth or to a method of preparing a pharmaceutical/cosmetic composition, Inventions IV-VIII are drawn to a method for treating a human being affected by a hair growth disorder, comprising a step of administering a hair growth modulating substance. While the Inventions commonly are drawn to a growth modulating substance, the methods of identifying a substance that modulates hair growth, a method of preparing a pharmaceutical/cosmetic composition, and a method of treating a human being affected by a hair growth disorder require different method steps. The searches for Inventions I/II/III and IV-VIII are burdensome because the searches are not coextensive.

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Inventions I/II and IX-XX are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed identifies a variety of structurally different products: nucleic acid molecules, chemical compounds, and proteins. With particular regard to nucleic acid molecules, the method can be used to identify different kinds of nucleic acid molecules, including antisense-sgk-3 probe, sgk-3 RNAi, a nucleic acid that encodes a transdominant inhibitor SGK3, and a genetic construct comprising a coding region coding for sgk-3-derived segment under control of a promoter.

Inventions III and IX-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, in addition to using the compounds in a method of preparing a pharmaceutical/cosmetic composition, the compounds can be used in a method of treating a patient.

Inventions II and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, Invention II is drawn to a method of using an *sgk-3*^{-/-} animal in a screen for substances that modulate SGK-3, and Invention II is drawn to an *sgk-3*^{-/-} animal. In addition using the animal in a screen, the *sgk3*^{-/-} animal can be used in a method for studying the effects caused by disruption of *sgk-3* in an animal.

Inventions I, IV-VIII and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I, drawn to an in vitro method for identifying a hair growth modulating substance, does not depend on Invention XXI, drawn to a transgenic *sgk-3*^{-/-} animal. Inventions IV-VIII are drawn to methods of treating a human patient comprising administering a hair growth modulating substance. Inventions I, IV-VIII do not depend on Invention XXI and vice versa.

Inventions IX-XX and XXI are patentably distinct. While the *sgk-3*^{-/-} animal of Invention XXI was used in a method to obtain the substances of Inventions IX-XX, an animal is structurally different from a hair growth modulating substance. The searches for Inventions IX-XX and XXI are burdensome because the searches are not coextensive.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and that the search for one Invention is not required for another Invention, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.